

OVERVIEW OF CERTIFICATE OF NEED

Health Service Facilities Regulated by the CON Law [N.C.G.S.131E-175 (Article 9)]

1. General Acute Care Hospitals. [N.C.G.S. 131E-176(13)]
2. Inpatient Psychiatric Hospitals. [N.C.G.S. 131E-176(21)]
3. Inpatient Rehabilitation Hospitals. [N.C.G.S. 131E-176(22)]
4. Nursing Homes. [N.C.G.S. 131E-176(14d)]
5. Kidney Disease Treatment Centers (i.e., Certified End-Stage Renal Disease Facilities) [N.C.G.S. 131E-176(14a1)]
6. Intermediate Care Facilities for the Mentally Retarded [N.C.G.S. 131E-176(14a)]
7. Certified Home Health Agency Offices [N.C.G.S. 131E-176(12)]
8. Chemical Dependency Treatment Facilities (inpatient & residential) [N.C.G.S. 131E-176(5a)]
9. Diagnostic Centers. [N.C.G.S. 131E-176(7a)]
10. Hospice Programs. [N.C.G.S. 131E-176(13a)]
{Eff. January 1, 2006 development of any additional hospice office will be regulated.}
11. Hospice Inpatient Facilities. [N.C.G.S. 131E-176(13b)]
12. Hospice Residential Care Facilities. [N.C.G.S. 131E-176(13c)]
13. Ambulatory Surgical Facilities. [N.C.G.S. 131E-176(1a)]
14. Adult Care Homes [N.C.G.S. 131E-176(12a)]
15. Long-Term Care Hospitals [N.C.G.S. 131E-176(14c1)]

Activities Requiring Certificate of Need Review [N.C.G.S. §131E-175(Article 9)]

- (a) Establishment of a new health service facility (See 1 through 15 above). [N.C.G.S. 131E-176(16)a]
- (b) Capital expenditure by any person for health service in excess of \$2 million dollars. [N.C.G.S. 131E-176(16)b]
- (c) Change in bed capacity. [N.C.G.S. 131E 176(16)c, 176(5) and 176(9c)]
 - (i) Relocation of health service facility beds or dialysis stations. [N.C.G.S. 131E-176(16)(5)(i)]
 - (ii) Change of health service facility beds from one category to another. [N.C.G.S. 131E-176(5)(ii)]
 - (iii) Increase in dialysis stations or health service facility beds. [N.C.G.S. 131E-176(5)(iii)]

Health service facility beds are defined in N.C.G.S. 131E-176(9c) to include:

- a. acute care beds;
 - b. inpatient psychiatric beds;
 - c. inpatient rehabilitation beds;
 - d. nursing home beds;
 - e. intermediate care beds for the mentally retarded;
 - f. chemical dependency treatment beds, including inpatient and residential;
 - g. hospice inpatient facility beds;
 - h. hospice residential care facility beds;
 - i. adult care home beds; and
 - j. long-term care hospital beds.
- (d) Establishment of new dialysis services or home health services. [N.C.G.S. 131E-176(16)d]
 - (e) Change in project that includes cost overrun of 15% of the capital expenditure amount of an approved CON project or addition of a health service to an approved project. [N.C.G.S. 131E-176(16)e]

- (f) The offering of any of the following services [N.C.G.S. 131E-176(16)f]:
 - a. Bone marrow transplantation;
 - b. Burn intensive care services;
 - c. Neonatal intensive care services (NICU);
 - d. Open-heart surgery services;
 - e. Solid organ transplantation services; and
 - f. Cardiac catheterization services.
- (f1) The acquisition of any of the following equipment [N.C.G.S. 131E-176(16)f1]:
 - a. Air ambulance;
 - b. Cardiac catheterization equipment;
 - c. Gamma knife equipment;
 - d. Heart-lung bypass machine;
 - e. Linear Accelerator;
 - f. Lithotripter;
 - g. Magnetic Resonance Imaging scanner;
 - h. Positron Emission Tomography (PET) scanner; and
 - i. Simulator.
- (g-k) Repealed.
- (l) The acquisition of a health service facility from a health maintenance organization. [N.C.G.S. 131E-176(16)l]
- (m) Conversion of non-health care beds to health care beds. [N.C.G.S. 131E-176(16)m]
- (n) Construction, development or establishment of a hospice, hospice inpatient facility, or hospice residential care facility. [N.C.G.S. 131E-176(16)n]
- (o) Opening of an additional office by an existing home health agency or hospice. [N.C.G.S. 131E-176(16)o]
- (p) Acquisition of major medical equipment (\$750,000 including costs of studies, design, construction, renovation and installation). [N.C.G.S. 131E-176(14f)]
- (q) Relocation of a health service facility from one service area to another. [N.C.G.S. 131E-176(16)q and 176(24a)]
- (r) Conversion of specialty ambulatory surgical program to a multispecialty ambulatory surgical program or the addition of a specialty to a specialty ambulatory surgical program. [N.C.G.S. 131E-176(16)r, 176(15a) and 176(24c)]
- (s) Furnishing mobile medical equipment to any person in North Carolina if not in use in North Carolina prior to March 18, 1993. [N.C.G.S. 131E-176(16)s]
- (t) Repealed.
- (u) The construction, development, establishment, increase in the number, or relocation of an operating room or gastrointestinal endoscopy room in a licensed health service facility, other than relocation within the same building or on the same grounds or to grounds not separated by more than a public right of way from existing location [N.C.G.S. 131E-176(16)u]
- (v) The change in designation, in a licensed health service facility, of an operating room to a gastrointestinal endoscopy room or change in designation of a gastrointestinal endoscopy room to an operating room that results in a different number of each type of room than is reflected on the health service facility's license in effect as of January 1, 2005.

Article 9
Certificate of Need

[Last Updated 9-1-05]

§ 131E-175. Findings of fact.

The General Assembly of North Carolina makes the following findings:

- (1) That the financing of health care, particularly the reimbursement of health services rendered by health service facilities, limits the effect of free market competition and government regulation is therefore necessary to control costs, utilization, and distribution of new health service facilities and the bed complements of these health service facilities.
- (2) That the increasing cost of health care services offered through health service facilities threatens the health and welfare of the citizens of this State in that citizens need assurance of economical and readily available health care.
- (3) That, if left to the market place to allocate health service facilities and health care services, geographical maldistribution of these facilities and services would occur and, further, less than equal access to all population groups, especially those that have traditionally been medically underserved, would result.
- (3a) That access to health care services and health care facilities is critical to the welfare of rural North Carolinians, and to the continued viability of rural communities, and that the needs of rural North Carolinians should be considered in the certificate of need review process.
- (4) That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.
- (5) Repealed.
- (6) That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.
- (7) That the general welfare and protection of lives, health, and property of the people of this State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria as determined by provisions of this Article or by the North Carolina Department of Health and Human Services pursuant to provisions of this Article prior to such services being offered or developed in order that only appropriate and needed institutional health services are made available in the area to be served.
- (8) That because persons who have received exemptions under Section 11.9(a) of S.L. 2000-67, as amended, and under Section 11.69(b) of S.L. 1997-443, as amended by Section 12.16C(a) of S.L. 1998-212, and as amended by Section 1 of S.L. 1999-135, have had sufficient time to complete development plans and initiate construction of beds in adult care homes.
- (9) That because with the enactment of this legislation, beds allowed under the exemptions noted above and pending development will count in the inventory of adult care home beds available to provide care to residents in the State Medical Facilities Plan.
- (10) That because State and county expenditures provide support for nearly three-quarters of the residents in adult care homes through the State County Special Assistance program, and excess bed capacity increases costs per resident day, it is in the public interest to promote efficiencies in delivering care in those facilities by controlling and directing their growth in an effort to prevent underutilization and higher costs and provide appropriate geographical distribution.

- (11) That physicians providing gastrointestinal endoscopy services in unlicensed settings should be given an opportunity to obtain a license to provide those services to ensure the safety of patients and the provision of quality care.
- (12) That demand for gastrointestinal endoscopy services is increasing at a substantially faster rate than the general population given the procedure is recognized as a highly effective means to diagnose and prevent cancer.

§ 131E-176. Definitions.

As used in this Article, unless the context clearly requires otherwise, the following terms have the meanings specified:

- (1) "Adult care home" means a facility with seven or more beds licensed under G.S. 131D-2 or Chapter 131E of the General Statutes that provides residential care for aged or disabled persons whose principal need is a home which provides the supervision and personal care appropriate to their age and disability and for whom medical care is only occasional or incidental.
- (1a) "Air ambulance" means aircraft used to provide air transport of sick or injured persons between destinations within the State.
- (1b) "Ambulatory surgical facility" means a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. An ambulatory surgical facility may only admit patients for a period of less than 24 hours and must provide at least one designated operating room **or gastrointestinal endoscopy room, as defined in Article 5 Part 1 and Article 6, Part 4 of this Chapter**, and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision **(1c) of this section** and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility.
- (1c) "Ambulatory surgical program" means a formal program for providing on a same-day basis those surgical procedures which require local, regional or general anesthesia and a period of post-operative observation to patients whose admission for more than 24 hours is determined, prior to surgery **or gastrointestinal endoscopy**, to be medically unnecessary.
- (2) "Bed capacity" means space used exclusively for inpatient care, including space designed or remodeled for licensed inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by rules of the Department except that single beds in single rooms are counted even if the room contains inadequate square footage. The term "bed capacity" also refers to the number of dialysis stations in kidney disease treatment centers, including freestanding dialysis units.
- (2a) "Bone marrow transplantation services" means the process of infusing bone marrow into persons with diseases to stimulate the production of blood cells.
- (2b) "Burn intensive care services" means services provided in a unit designed to care for patients who have been severely burned.

- (2c) "Campus" means the adjacent grounds and buildings, or grounds and buildings not separated by more than a public right-of-way, of a health service facility and related health care entities.
- (2d) "Capital expenditure" means an expenditure for a project, including but not limited to the cost of construction, engineering, and equipment which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance. Capital expenditure includes, in addition, the fair market value of an acquisition made by donation, lease, or comparable arrangement by which a person obtains equipment, the expenditure for which would have been considered a capital expenditure under this Article if the person had acquired it by purchase.
- (2e) **Repealed. 8-26-05**
- (2f) "Cardiac catheterization equipment" means the equipment **used to provide cardiac catheterization services.**
- (2g) **"Cardiac catheterization services" means those procedures, excluding pulmonary angiography procedures, in which a catheter is introduced into a vein or artery and threaded through the circulatory system into the heart specifically to diagnose abnormalities in the motion, contraction, and blood flow of the moving heart or to perform surgical therapeutic interventions to restore, repair, or reconstruct the coronary blood vessels of the heart.**
- (3) "Certificate of need" means a written order which affords the person so designated as the legal proponent of the proposed project the opportunity to proceed with the development of such project.
- (4) Repealed.
- (5) "Change in bed capacity" means (i) any relocation of health service facility beds, or dialysis stations from one licensed facility or campus to another, or (ii) any redistribution of health service facility bed capacity among the categories of health service facility bed as defined in G.S. 131E-176(9c), or (iii) any increase in the number of health service facility beds, or dialysis stations in kidney disease treatment centers, including freestanding dialysis units.
- (5a) "Chemical dependency treatment facility" means a public or private facility, or unit in a facility, which is engaged in providing 24-hour a day treatment for chemical dependency or substance abuse. This treatment may include detoxification, administration of a therapeutic regimen for the treatment of chemically dependent or substance abusing persons and related services. The facility or unit may be:
 - a. A unit within a general hospital or an attached or freestanding unit of a general hospital licensed under Article 5, Chapter 131E, of the General Statutes,
 - b. A unit within a psychiatric hospital or an attached or freestanding unit of a psychiatric hospital licensed under Article 1A of General Statutes Chapter 122 or Article 2 of General Statutes Chapter 122C,
 - c. A freestanding facility specializing in treatment of persons who are substance abusers or chemically dependent licensed under Article 1A of General Statutes Chapter 122 or Article 2 of General Statutes Chapter 122C; and may be identified as "chemical dependency, substance abuse, alcoholism, or drug abuse treatment units," "residential chemical dependency, substance abuse, alcoholism or drug abuse facilities," or by other names if the purpose is to provide treatment of chemically dependent or substance abusing persons, but shall not include social setting detoxification facilities, medical detoxification facilities, halfway houses or recovery farms.
- (5b) "Chemical dependency treatment beds" means beds that are licensed for the inpatient treatment of chemical dependency. Residential treatment beds for the treatment of chemical dependency or substance abuse are chemical dependency treatment beds. Chemical dependency treatment beds shall not include beds licensed for detoxification.
- (6) "Department" means the North Carolina Department of Health and Human Services.

- (7) To "develop" when used in connection with health services, means to undertake those activities which will result in the offering of institutional health service or the incurring of a financial obligation in relation to the offering of such a service.
- (7a) "Diagnostic center" means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.
- (7b) "Expedited review" means the status given to an application's review process when the applicant petitions for the review and the Department approves the request based on findings that all of the following are met:
 - a. The review is not competitive.
 - b. The proposed capital expenditure is less than five million dollars (\$5,000,000).
 - c. A request for a public hearing is not received within the time frame defined in G.S. 131E-185.
 - d. The agency has not determined that a public hearing is in the public interest.
- (7c) "Gamma knife" means equipment which emits photon beams from a stationary radioactive cobalt source to treat lesions deep within the brain and is one type of stereotactic radiosurgery.
- (7d) **"Gastrointestinal endoscopy room" means a room used for the performance of procedures that require the insertion of a flexible endoscope into a gastrointestinal orifice to visualize the gastrointestinal lining and adjacent organs for diagnostic or therapeutic purposes.**
- (8), Repealed.
- (9a) "Health service" means an organized, interrelated medical, diagnostic, therapeutic, and/or rehabilitative activity that is integral to the prevention of disease or the clinical management of a sick, injured, or disabled person. "Health service" does not include administrative and other activities that are not integral to clinical management.
- (9b) "Health service facility" means a hospital; **long-term care hospital**; psychiatric facility; rehabilitation facility; nursing home facility; adult care home; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for the mentally retarded; home health agency office; chemical dependency treatment facility; diagnostic center; **hospice office**, hospice inpatient facility, hospice residential care facility; and ambulatory surgical facility.
- (9c) "Health service facility bed" means a bed licensed for use in a health service facility in the categories of (i) acute care beds; (ii) psychiatric beds; (iii) rehabilitation beds; (iv) nursing home beds; (v) intermediate care beds for the mentally retarded; (vi) chemical dependency treatment beds; (vii) hospice inpatient facility beds; (viii) hospice residential care facility beds; (ix) adult care home beds; and (x) **long-term care hospital beds**.
- (10) "Health maintenance organization (HMO)" means a public or private organization which has received its certificate of authority under Article 67 of Chapter 58 of the General Statutes and which either is a qualified health maintenance organization under Section 1310(d) of the Public Health Service Act or:
 - a. Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual

- physician services, hospitalization, laboratory, X ray, emergency and preventive services, and out-of-area coverage;
- b. Is compensated, except for copayments, for the provision of the basic health care services listed above to enrolled participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and
 - c. Provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organizations, or (ii) through arrangements with individual physicians or one or more groups of physicians organized on a group practice or individual practice basis.
- (10a) "Heart-lung bypass machine" means the equipment used to perform extra-corporeal circulation and oxygenation during surgical procedures.
- (11) Repealed
- (12) "Home health agency" means a private organization or public agency, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services.
- "Home health services" means items and services furnished to an individual by a home health agency, or by others under arrangements with such others made by the agency, on a visiting basis, and except for paragraph e. of this subdivision, in a place of temporary or permanent residence used as the individual's home as follows:
- a. Part-time or intermittent nursing care provided by or under the supervision of a registered nurse;
 - b. Physical, occupational or speech therapy;
 - c. Medical social services, home health aid services, and other therapeutic services;
 - d. Medical supplies, other than drugs and biologicals and the use of medical appliances;
 - e. Any of the foregoing items and services which are provided on an outpatient basis under arrangements made by the home health agency at a hospital or nursing home facility or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in his home, or which are furnished at such facility while he is there to receive any such item or service, but not including transportation of the individual in connection with any such item or service.
- (13) "Hospital" means a public or private institution which is primarily engaged in providing to inpatients, by or under supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. The term includes all facilities licensed pursuant to G.S. 131E-77 of the General Statutes, **except long-term care hospitals.**
- (13a) "Hospice" means any coordinated program of home care with provision for inpatient care for terminally ill patients and their families. This care is provided by a medically directed interdisciplinary team, directly or through an agreement under the direction of an identifiable hospice administration. A hospice program of care provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual and special needs of patients and their families, which are experienced during the final stages of terminal illness and during dying and bereavement.
- (13b) "Hospice inpatient facility" means a freestanding licensed hospice facility or a designated inpatient unit in an existing health service facility which provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual, and special needs of terminally ill patients and their

families in an inpatient setting. For purposes of this Article only, a hospital which has a contractual agreement with a licensed hospice to provide inpatient services to a hospice patient as defined in G.S. 131E-201(4) and provides those services in a licensed acute care bed is not a hospice inpatient facility and is not subject to the requirements in G.S. 131E-176(5)(ii) for hospice inpatient beds.

- (13c) "Hospice residential care facility" means a freestanding licensed hospice facility which provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual, and special needs of terminally ill patients and their families in a group residential setting.
- (14) Repealed.
- (14a) "Intermediate care facility for the mentally retarded" means facilities licensed pursuant to Article 2 of Chapter 122C of the General Statutes for the purpose of providing health and habilitative services based on the developmental model and principles of normalization for persons with mental retardation, autism, cerebral palsy, epilepsy or related conditions.
- (14a1) **"Kidney disease treatment center" means a facility that is certified as an end-stage renal disease facility by the Centers for Medicare and Medicaid Services, Department of Health and Human Services, pursuant to 42 C.F.R. § 405.**
- (14b) Repealed.
- (14b1) **"Linear accelerator" means a machine used to produce ionizing radiation in excess of 1,000,000 electron volts in the form of a beam of electrons or photons to treat cancer patients.**
- (14c) "Lithotripter" means extra-corporeal shock wave technology used to treat persons with kidney stones and gallstones.
- (14c1) **"Long-term care hospital" means a hospital that has been classified and designated as a long-term care hospital by the Centers for Medicare and Medicaid Services, Department of Health and Human Services, pursuant to 42 C.F.R. § 412.**
- (14d) Repealed.
- (14e) "Magnetic resonance imaging scanner" means medical imaging equipment that uses nuclear magnetic resonance.
- (14f) "Major medical equipment" means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.
- (15) Repealed.
- (15a) "Multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.
- (15b) "Neonatal intensive care services" means those services provided by a health service facility to high-risk newborn infants who require constant nursing care, including but not limited to continuous cardiopulmonary and other supportive care.
- (16) "New institutional health services" means any of the following:
 - a. The construction, development, or other establishment of a new health service facility.

- b. The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).
- c. Any change in bed capacity as defined in G.S. 131E-176(5).
- d. The offering of dialysis services or home health services by or on behalf of a health service facility if those services were not offered within the previous 12 months by or on behalf of the facility.
- e. A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed. For purposes of this subdivision, a change in a project is a change of more than fifteen percent (15%) of the approved capital expenditure amount or the addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in the project.
- f. The development or offering of a health service as listed in this subdivision by or on behalf of any person:
 - 1. Bone marrow transplantation services.
 - 2. Burn intensive care services.
 - 2a. Cardiac catheterization services, except cardiac catheterization services provided on equipment furnished by a person authorized to operate such equipment in North Carolina pursuant to either a certificate of need issued for mobile cardiac catheterization equipment or a settlement agreement executed by the Department for provision of cardiac catheterization services.**
 - 3. Neonatal intensive care services.
 - 4. Open-heart surgery services.
 - 5. Solid organ transplantation services.
- f1. The acquisition by purchase, donation, lease, transfer, or comparable arrangement of any of the following equipment by or on behalf of any person:
 - 1. Air ambulance.
 - 2. Repealed.**
 - 3. Cardiac catheterization equipment.
 - 4. Gamma knife.
 - 5. Heart-lung bypass machine.
 - 5a. Linear accelerator.**
 - 6. Lithotripter.
 - 7. Magnetic resonance imaging scanner.
 - 8. Positron emission tomography scanner.
 - 9. Simulator.**
- g. to k. Repealed.
- 1. The purchase, lease, or acquisition of any health service facility, or portion thereof, or a controlling interest in the health service facility or portion thereof, if the health service facility was developed under a certificate of need issued pursuant to G.S. 131E-180.
- m. Any conversion of nonhealth service facility beds to health service facility beds.
- n. The construction, development or other establishment of a hospice, hospice inpatient facility, or hospice residential care facility;

- o. The opening of an additional office by an existing home health agency **or hospice** within its service area as defined by rules adopted by the Department; or the opening of any office by an existing home health agency **or hospice** outside its service area as defined by rules adopted by the Department.
 - p. The acquisition by purchase, donation, lease, transfer, or comparable arrangement by any person of major medical equipment.
 - q. The relocation of a health service facility from one service area to another.
 - r. The conversion of a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or the addition of a specialty to a specialty ambulatory surgical program.
 - s. The furnishing of mobile medical equipment to any person to provide health services in North Carolina, which was not in use in North Carolina prior to the adoption of this provision, if such equipment would otherwise be subject to review in accordance with G.S. 131E-176(16)(f1.) or G.S. 131E-176(16)(p) if it had been acquired in North Carolina.
 - t. Repealed.
 - u. The construction, development, establishment, increase in the number, or relocation of an operating room or **gastrointestinal endoscopy room in a licensed health service facility**, other than the relocation of an operating room or **gastrointestinal endoscopy room** within the same building or on the same grounds or to grounds not separated by more than a public right-of-way adjacent to the grounds where the operating room is or **gastrointestinal endoscopy room** is currently located.
 - v. **The change in designation, in a licensed health service facility, of an operating room to a gastrointestinal endoscopy room or change in designation of a gastrointestinal endoscopy room to an operating room that results in a different number of each type of room than is reflected on the health service facility's license in effect as of January 1, 2005.**
- (17) "North Carolina State Health Coordinating Council" means the Council that prepares, with the Department of Health and Human Services, the State Medical Facilities Plan.
- (17a) "Nursing care" means:
- a. Skilled nursing care and related services for residents who require medical or nursing care;
 - b. Rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or
 - c. Health-related care and services provided on a regular basis to individuals who because of their mental or physical condition require care and services above the level of room and board, which can be made available to them only through institutional facilities.
- These are services which are not primarily for the care and treatment of mental diseases.
- (17b) "Nursing home facility" means a health service facility whose bed complement of health service facility beds is composed principally of nursing home facility beds.
- (18) To "offer," when used in connection with health services, means that the person holds himself out as capable of providing, or as having the means for the provision of, specified health services.
- (18a) Repealed. 8-26-05**
- (18b) "Open-heart surgery services" means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.

- (18c) **“Operating room” means a room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room.**
- (19) "Person" means an individual, a trust or estate, a partnership, a corporation, including associations, joint stock companies, and insurance companies; the State, or a political subdivision or agency or instrumentality of the State.
- (19a) "Positron emission tomography scanner" means equipment that utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures.
- (20) "Project" or "capital expenditure project" means a proposal to undertake a capital expenditure that results in the offering of a new institutional health service as defined by this Article. A project, or capital expenditure project, or proposed project may refer to the project from its earliest planning stages up through the point at which the specified new institutional health service may be offered. In the case of facility construction, the point at which the new institutional health service may be offered must take place after the facility is capable of being fully licensed and operated for its intended use, and at that time it shall be considered a health service facility.
- (21) "Psychiatric facility" means a public or private facility licensed pursuant to Article 2 of Chapter 122C of the General Statutes and which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.
- (22) "Rehabilitation facility" means a public or private inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent, professional supervision.
- (22a) "Replacement equipment" means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than two million dollars (\$2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.
- (23) Repealed.
- (24) Repealed.
- (24a) "Service area" means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.
- (24a1) **“Simulator” means a machine that produces high quality diagnostic radiographs and precisely reproduces the geometric relationships of megavoltage radiation therapy equipment to the patient.**
- (24b) "Solid organ transplantation services" means the provision of surgical procedures and the interrelated medical services that accompany the surgery to remove an organ from a patient and surgically implant an organ from a donor.
- (24c) "Specialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for only the specialty areas identified on the ambulatory surgical facility's 1993 Application for Licensure as an Ambulatory Surgical Center and authorized by its certificate of need.
- (25) "State Medical Facilities Plan" means the plan prepared by the Department of Health and Human Services and the North Carolina State Health Coordinating Council, and approved by the Governor. In preparing the Plan, the Department and the State Health Coordinating Council shall maintain a mailing list of persons who have

requested notice of public hearings regarding the Plan. Not less than 15 days prior to a scheduled public hearing, the Department shall notify persons on its mailing list of the date, time, and location of the hearing. The Department shall hold at least one public hearing prior to the adoption of the proposed Plan and at least six public hearings after the adoption of the proposed Plan by the State Health Coordinating Council. The Council shall accept oral and written comments from the public concerning the Plan.

(26) Repealed.

(27) Repealed.

§ 131E-177. Department of Health and Human Services is designated State Health Planning and Development Agency; powers and duties.

The Department of Health and Human Services is designated as the State Health Planning and Development Agency for the State of North Carolina, and is empowered to exercise the following powers and duties:

- (1) To establish standards and criteria or plans required to carry out the provisions and purposes of this Article and to adopt rules pursuant to Chapter 150B of the General Statutes, to carry out the purposes and provisions of this Article;
- (2) Adopt, amend, and repeal such rules and regulations, consistent with the laws of this State, as may be required by the federal government for grants-in-aid for health service facilities and health planning which may be made available by the federal government. This section shall be liberally construed in order that the State and its citizens may benefit from such grants-in-aid;
- (3) Define, by rule, procedures for submission of periodic reports by persons or health service facilities subject to agency review under this Article;
- (4) Develop policy, criteria, and standards for health service facilities planning; shall conduct statewide registration and inventories of and make determinations of need for health service facilities, health services as specified in G.S. 131E-176(16)f., and equipment as specified in G.S. 131E-176(16)f1., which shall include consideration of adequate geographic location of equipment and services; and develop a State Medical Facilities Plan;
- (5) Implement, by rule, criteria for project review;
- (6) Have the power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article;
- (7) Solicit, accept, hold and administer on behalf of the State any grants or bequests of money, securities or property to the Department for use by the Department in the administration of this Article; and
- (8) Repealed.
- (9) Establish and collect fees for submitting applications for certificates of need. The fee schedule established should generate sufficient revenue to offset the entire cost of the certificate of need program. This fee may not exceed seventeen thousand five hundred dollars (\$17,500) and may not be less than two thousand dollars (\$2,000). Fees collected under this subdivision shall be credited to the General Fund as nontax revenue.
- (10) The authority to review all records in any recording medium of any person or health service facility subject to agency review under this Article which pertain to construction and acquisition activities, staffing or costs and charges for patient care, including but not limited to, construction contracts, architectural contracts, consultant contracts, purchase orders, cancelled checks, accounting and financial records, debt instruments, loan and security agreements, staffing records, utilization statistics and any other records the Department deems to be reasonably necessary to determine compliance with this Article.

The Secretary of Health and Human Services shall have final decision-making authority with regard to all functions described in this section.

§ 131E-178. Activities requiring certificate of need.

(a) No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department; provided, however, **no person who provides gastrointestinal endoscopy procedures in one or more gastrointestinal endoscopy rooms located in a nonlicensed setting, shall be required to obtain a certificate of need to license that setting as an ambulatory surgical facility with the existing number of gastrointestinal endoscopy rooms, provided that:**

- (1) **The license application is postmarked for delivery to the Division of Facility Services by December 31, 2006;**
- (2) **The applicant verifies, by affidavit submitted to the Division of Facility Services within 60 days of the effective date of this act, that the facility is in operation as of the effective date of this act or that the completed application for the building permit for the facility was submitted by the effective date of this act;**
- (3) **The facility has been accredited by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities by the time the license application is postmarked for delivery to the Division of Facility Services of the Department; and**
- (4) **The license application includes a commitment and plan for serving indigent and medically underserved populations.**

All other persons proposing to obtain a license to establish an ambulatory surgical facility for the provision of gastrointestinal endoscopy procedures shall be required to obtain a certificate of need. The annual State Medical Facilities Plan shall not include policies or need determinations that limit the number of gastrointestinal endoscopy rooms that may be approved.

(b) No person shall make an acquisition by donation, lease, transfer, or comparable arrangement without first obtaining a certificate of need from the Department, if the acquisition would have been a new institutional health service if it had been made by purchase. In determining whether an acquisition would have been a new institutional health service, the capital expenditure for the asset shall be deemed to be the fair market value of the asset or the cost of the asset, whichever is greater.

(c) No person shall incur an obligation for a capital expenditure which is a new institutional health service without first obtaining a certificate of need from the Department. An obligation for a capital expenditure is incurred when:

- (1) An enforceable contract, excepting contracts which are expressly contingent upon issuance of a certificate of need, is entered into by a person for the construction, acquisition, lease or financing of a capital asset;
- (2) A person takes formal action to commit funds for a construction project undertaken as his own contractor; or
- (3) In the case of donated property, the date on which the gift is completed.

(d) Where the estimated cost of a proposed capital expenditure, including the fair market value of equipment acquired by purchase, lease, transfer, or other comparable arrangement, is certified by a licensed architect or engineer to be equal to or less than the expenditure minimum for capital expenditure for new institutional health services, such expenditure shall be deemed not to exceed the amount for new institutional health services regardless of the actual amount expended, provided that the following conditions are met:

- (1) The certified estimated cost is prepared in writing 60 days or more before the obligation for the capital expenditure is incurred. Certified cost estimates shall be available for inspection at the facility and sent to the Department upon its request.

- (2) The facility on whose behalf the expenditure was made notifies the Department in writing within 30 days of the date on which such expenditure is made if the expenditure exceeds the expenditure minimum for capital expenditures. The notice shall include a copy of the certified cost estimate.

(e) The Department may grant certificates of need which permit capital expenditures only for predevelopment activities. Predevelopment activities include the preparation of architectural designs, plans, working drawings, or specifications, the preparation of studies and surveys, and the acquisition of a potential site.

§ 131E-179. Research activities.

(a) Notwithstanding any other provisions of this Article, a health service facility may offer new institutional health services to be used solely for research, or incur the obligation of a capital expenditure solely for research, without a certificate of need, if the Department grants an exemption. The Department shall grant an exemption if the health service facility files a notice of intent with the Department in accordance with rules promulgated by the Department and if the Department finds that the offering or obligation will not:

- (1) Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;
- (2) Substantially change the bed capacity of the facility; or
- (3) Substantially change the medical or other patient care services of the facility.

(b) After a health service facility has received an exemption pursuant to subsection (a) of this section, it shall not offer the new institutional health services, or use a facility acquired through the capital expenditure, in a manner which affects the charges of the facility for the provision of medical or other patient care services, other than the services which are included in the research and shall not charge patients for the use of the service for which an exemption has been granted, without first obtaining a certificate of need from the Department; provided, however, that any facility or service acquired or developed under the exemption provided by this section shall not be subject to the foregoing restrictions on its use if the facility or service could otherwise be offered or developed without a certificate of need.

(c) Any of the activities described in subsection (a) of this section shall be deemed to be solely for research even if they include patient care provided on an occasional and irregular basis and not as a part of the research program.

§ 131E-180. Repealed. 8-26-05

§ 131E-181. Nature of certificate of need.

(a) A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).

(b) A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need. The Department shall require any recipient of a certificate of need, or its successor, whose service is in operation to submit to the Department evidence that the recipient, or its successor, is in material compliance with the representations made in its application for the certificate of need which granted the recipient the right to operate that service. In determining whether the recipient of a certificate of need, or its successor, is operating a service which materially differs from the representations made in its application for that certificate of need, the Department shall consider cost increases to the recipient, or its successor, including, but not limited to, the following:

- (1) Any increase in the consumer price index;
- (2) Any increased cost incurred because of Government requirements, including federal, State, or any political subdivision thereof; and

(3) Any increase in cost due to professional fees or the purchase of services and supplies.

(c) Whenever a certificate of need is issued more than 12 months after the application for the certificate of need began review, the Department shall adjust the capital expenditure amount proposed by increasing it to reflect any inflation in the Department of Commerce's Construction Cost Index that has occurred since the date when the application began review; and the Department shall use this recalculated capital expenditure amount in the certificate of need issued for the project.

(d) A project authorized by a certificate of need is complete when the health service or the health service facility for which the certificate of need was issued is licensed and certified and is in material compliance with the representations made in the certificate of need application.

§ 131E-182. Application.

(a) The Department in its rules shall establish schedules for submission and review of completed applications. The schedules shall provide that applications for similar proposals in the same service area will be reviewed together. **However, there shall not be a review schedule prior to February 1, 2006, for submission and review of certificate of need applications that propose an increase in the number of licensed gastrointestinal endoscopy rooms. An applicant for a certificate of need to establish a licensed gastrointestinal endoscopy room shall show that it is performing or reasonably projects to perform at least 1,500 gastrointestinal endoscopy procedures per gastrointestinal endoscopy room per year.**

(b) An application for a certificate of need shall be made on forms provided by the Department. The application forms, which may vary according to the type of proposal, shall require such information as the Department, by its rules deems necessary to conduct the review. An applicant shall be required to furnish only that information necessary to determine whether the proposed new institutional health service is consistent with the review criteria implemented under G.S. 131E-183 and with duly adopted standards, plans and criteria.

(c) All fees established by the Department for submitting an application for a certificate of need are due when the application is submitted. These fees are not refundable, regardless of whether a certificate of need is issued.

§ 131E-183. Review criteria.

(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

(2) Repealed.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.
- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.
- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.
- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.
- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:
 - a. The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
 - b. The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 1. Would be available under a contract of at least five years' duration;
 2. Would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 3. Would cost no more than if the services were provided by the HMO; and
 4. Would be available in a manner which is administratively feasible to the HMO.
- (11) Repealed
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.
- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- a. The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;
 - b. Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;
 - c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and
 - d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.
- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.
- (15) through (18) Repealed.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.
- (19) Repealed.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.
- (21) Repealed.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

(c) Repealed.

§ 131E-184. Exemptions from review.

(a) Except as provided in subsection (b), the Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required, for any of the following:

- (1) To eliminate or prevent imminent safety hazards as defined in federal, State, or local fire, building, or life safety codes or regulations.
- (1a) To comply with State licensure standards.
- (1b) To comply with accreditation or certification standards which must be met to receive reimbursement under Title XVIII of the Social Security Act or payments under a State plan for medical assistance approved under Title XIX of that act.
- (2) Repealed.

- (3) To provide data processing equipment.
- (4) To provide parking, heating or cooling systems, elevators, or other basic plant or mechanical improvements, unless these activities are integral portions of a project that involves the construction of a new health service facility or portion thereof and that is subject to certificate of need review.
- (5) To replace or repair facilities destroyed or damaged by accident or natural disaster.
- (6) To provide any nonhealth service facility or service.
- (7) To provide replacement equipment.
- (8) To acquire an existing health service facility, including equipment owned by the health service facility at the time of acquisition.
- (9) To develop or acquire a physician office building regardless of cost, unless a new institutional health service other than defined in G.S. 131E-176(16)b. is offered or developed in the building.

(b) Those portions of a proposed project which are not proposed for one or more of the purposes under subsection (a) of this section are subject to certificate of need review, if these non-exempt portions of the project are new institutional health services under G.S. 131E-176(16).

(c) The Department shall exempt from certificate of need review any conversion of existing acute care beds to psychiatric beds provided:

- (1) The hospital proposing the conversion has executed a contract with the Department's Division of Mental Health, Developmental Disabilities, and Substance Abuse Services and/or one or more of the Area Mental Health, Developmental Disabilities, and Substance Abuse Authorities to provide psychiatric beds to patients referred by the contracting agency or agencies; and
- (2) The total number of beds to be converted shall not be more than twice the number of beds for which the contract pursuant to subdivision (1) of this subsection shall provide.

(d) In accordance with, and subject to the limitations of G.S. 148-19.1, the Department shall exempt from certificate of need review the construction and operation of a new chemical dependency or substance abuse facility for the purpose of providing inpatient chemical dependency or substance abuse services solely to inmates of the Department of Correction. If an inpatient chemical dependency or substance abuse facility provides services both to inmates of the Department of Correction and to members of the general public, only the portion of the facility that serves inmates shall be exempt from certificate of need review.

§ 131E-185. Review process.

(a) Repealed.

(a1) Except as provided in subsection (c) of this section, there shall be a time limit of 90 days for review of the applications, beginning on the day established by rule as the day on which applications for the particular service in the service area shall begin review.

- (1) Any person may file written comments and exhibits concerning a proposal under review with the Department, not later than 30 days after the date on which the application begins review. These written comments may include:
 - a. Facts relating to the service area proposed in the application;
 - b. Facts relating to the representations made by the applicant in its application, and its ability to perform or fulfill the representations made;
 - c. Discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with relevant review criteria, plans, and standards.
- (2) No more than 20 days from the conclusion of the written comment period, the Department shall ensure that a public hearing is conducted at a place within the appropriate service area if one or more of the following circumstances apply; the review to be conducted is competitive; the proponent proposes to spend five million

dollars (\$5,000,000) or more; a written request for a public hearing is received before the end of the written comment period from an affected party as defined in G.S. 131E-188(c); or the agency determines that a hearing is in the public interest. At such public hearing oral arguments may be made regarding the application or applications under review; and this public hearing shall include the following:

- a. An opportunity for the proponent of each application under review to respond to the written comments submitted to the Department about its application;
- b. An opportunity for **any person**, except one of the proponents, to **comment on** the applications under review;
- c. An opportunity for a representative of the Department, or such other person or persons who are designated by the Department to conduct the hearing, to question each proponent of applications under review with regard to the contents of the application;

The Department shall maintain a recording of any required public hearing on an application until such time as the Department's final decision is issued, or until a final agency decision is issued pursuant to a contested case hearing, whichever is later; and any person may submit a written synopsis or verbatim statement that contains the oral presentation made at the hearing.

- (3) The Department may contract or make arrangements with a person or persons located within each service area for the conduct of such public hearings as may be necessary. The Department shall publish, in each service area, notice of the contracts that it executes for the conduct of those hearings.
- (4) Within 15 days from the beginning of the review of an application or applications proposing the same service within the same service area, the Department shall publish notice of the deadline for receipt of written comments, of the time and place scheduled for the public hearing regarding the application or applications under review, and of the name and address of the person or agency that will preside.
- (5) The Department shall maintain all written comments submitted to it during the written comment stage and any written submissions received at the public hearing as part of the Department's file respecting each application or group of applications under review by it. The application, written comments, and public hearing comments, together with all documents that the Department used in arriving at its decision, from whatever source, and any documents that reflect or set out the Department's final analysis of the application or applications under review, shall constitute the Department's record for the application or applications under review.

(a2) When an expedited review has been approved by the Department, no public hearing shall be held. The Department may contact the applicant and request additional or clarifying information, amendments to, or substitutions for portions of the application. The Department may negotiate conditions to be imposed on the certificate of need with the applicant.

(b) Repealed.

(c) The Department may extend the review period for a period not to exceed 60 days and provide notice of such extension to all applicants. For expedited reviews, the Department may extend the review period only if it has requested additional substantive information from the applicant.

§ 131E-186. Decision.

(a) Within the prescribed time limits in G.S. 131E-185, the Department shall issue a decision to "approve," "approve with conditions," or "deny," an application for a new institutional health service. Approvals involving new or expanded nursing care or intermediate care for the mentally retarded bed capacity shall include a condition that specifies the earliest possible date the new institutional health service may be certified for participation in the Medicaid program. The date shall be set far enough in advance to allow the Department to identify funds to pay for care in the new or expanded facility in its

existing Medicaid budget or to include these funds in its State Medicaid budget request for the year in which Medicaid certification is expected.

(b) Within five business days after it makes a decision on an application, the Department shall provide written notice of all the findings and conclusions upon which it based its decision, including the criteria used by the Department in making its decision, to the applicant.

§ 131E-187. Issuance of a certificate of need.

(a) The Department shall issue a certificate of need within 35 days of the date of the decision referenced in G.S. 131E-186, when no request for a contested case hearing has been filed in accordance with G.S. 131E-188, and all applicable conditions of approval that can be satisfied before issuance of the certificate of need have been met.

(b) The Department shall issue a certificate of need within five days after a request for a contested case hearing has been withdrawn or the final agency decision has been made following a contested case hearing, and all applicable conditions of approval that can be satisfied before issuance of the certificate of need have been met.

§ 131E-188. Administrative and judicial review.

(a) After a decision of the Department to issue, deny or withdraw a certificate of need or exemption or to issue a certificate of need pursuant to a settlement agreement with an applicant to the extent permitted by law, any affected person, as defined in subsection (c) of this section, shall be entitled to a contested case hearing under Article 3 of Chapter 150B of the General Statutes. A petition for a contested case shall be filed within 30 days after the Department makes its decision. When a petition is filed, the Department shall send notification of the petition to the proponent of each application that was reviewed with the application for a certificate of need that is the subject of the petition. Any affected person shall be entitled to intervene in a contested case.

A contested case shall be conducted in accordance with the following timetable:

- (1) An administrative law judge or a hearing officer, as appropriate, shall be assigned within 15 days after a petition is filed.
- (2) The parties shall complete discovery within 90 days after the assignment of the administrative law judge or hearing officer.
- (3) The hearing at which sworn testimony is taken and evidence is presented shall be held within 45 days after the end of the discovery period.
- (4) The administrative law judge or hearing officer shall make his recommended decision within 75 days after the hearing.
- (5) The Department shall make its final decision within 30 days of receiving the official record of the case from the Office of Administrative Hearings.

The administrative law judge or hearing officer assigned to a case may extend the deadlines in subdivisions (2) through (4) so long as the administrative law judge or hearing officer makes his recommended decision in the case within 270 days after the petition is filed. The Department may extend the deadline in subdivision (5) for up to 30 days by giving all parties written notice of the extension.

(a1) On or before the date of filing a petition for a contested case hearing on the approval of an applicant for a certificate of need, the petitioner shall deposit a bond with the clerk of superior court where the new institutional health service that is the subject of the petition is proposed to be located. The bond shall be secured by cash or its equivalent in an amount equal to five percent (5%) of the cost of the proposed new institutional health service that is the subject of the petition, but may not be less than five thousand dollars (\$5,000) and may not exceed fifty thousand dollars (\$50,000). A petitioner who received approval for a certificate of need and is contesting only a condition in the certificate is not required to file a bond under this subsection.

The applicant who received approval for the new institutional health service that is the subject of the petition may bring an action against a bond filed under this subsection in the superior court of the county where the bond was filed. Upon finding that the petition for a contested case was frivolous or filed to

delay the applicant, the court may award the applicant part or all of the bond filed under this subsection. At the conclusion of the contested case, if the court does not find that the petition for a contested case was frivolous or filed to delay the applicant, the petitioner shall be entitled to the return of the bond deposited with the superior court upon demonstrating to the clerk of superior court where the bond was filed that the contested case hearing is concluded.

(b) Any affected person who was a party in a contested case hearing shall be entitled to judicial review of all or any portion of any final decision of the Department in the following manner. The appeal shall be to the Court of Appeals as provided in G.S. 7A-29(a). The procedure for the appeal shall be as provided by the rules of appellate procedure. The appeal of the final decision of the Department shall be taken within 30 days of the receipt of the written notice of final decision, and notice of appeal shall be filed with the Division of Facility Services, Department of Health and Human Services and served on all other affected persons who were parties to the contested hearing.

(b1) Before filing an appeal of a final decision by the Department granting a certificate of need, the affected person shall deposit a bond with the Clerk of the Court of Appeals. The bond shall be secured by cash or its equivalent in an amount equal to five percent (5%) of the cost of the proposed new institutional health service that is the subject of the appeal, but may not be less than five thousand dollars (\$5,000) and may not exceed fifty thousand dollars (\$50,000). A holder of a certificate of need who is appealing only a condition in the certificate is not required to file a bond under this subsection.

If the Court of Appeals finds that the appeal was frivolous or filed to delay the applicant, the court shall remand the case to the superior court of the county where a bond was filed for the contested case hearing on the certificate of need. The superior court may award the holder of the certificate of need part or all of the bond. The court shall award the holder of the certificate of need reasonable attorney fees and costs incurred in the appeal to the Court of Appeals. If the Court of Appeals does not find that the appeal was frivolous or filed to delay the applicant and does not remand the case to superior court for a possible award of all or part of the bond to the holder of the certificate of need, the person originally filing the bond shall be entitled to a return of the bond.

(c) The term "affected persons" includes: the applicant; any **individual** residing within the **service area or** the geographic area served or to be served by the applicant; any **individual** who regularly uses health service facilities within that geographic **area or the service area; any person who provides services, similar to the services under review, to individuals residing within the service area or the geographic area proposed to be served by the applicant; any person who, prior to receipt by the agency of the proposal being reviewed, has provided written notice to the agency of an intention to provide similar services in the future to individuals residing within the service area or the geographic area to be served by the applicant;** third party payers who reimburse health service facilities for services in the service area in which the project is proposed to be located; and any agency which establishes rates for health service facilities or HMOs located in the service area in which the project is proposed to be located.

§ 131E-189. Withdrawal of a certificate of need.

(a) The Department shall specify in each certificate of need the time the holder has to make the service or equipment available or to complete the project and the timetable to be followed. The timetable shall be the one proposed by the holder of the certificate of need unless the Department specifies a different timetable in its decision letter. The holder of the certificate shall submit such periodic reports on his progress in meeting the timetable as may be required by the Department. If no progress report is provided or, after reviewing the progress, the Department determines that the holder of the certificate is not meeting the timetable and the holder cannot demonstrate that it is making good faith efforts to meet the timetable, the Department may withdraw the certificate. If the Department determines that the holder of the certificate is making a good faith effort to meet the timetable, the Department may, at the request of the holder, extend the timetable for a specified period.

(b) The Department may withdraw any certificate of need, if the holder of the certificate fails to develop the service in a manner consistent with the representations made in the application or with any condition or conditions the Department placed on the certificate of need.

(c) The Department may immediately withdraw any certificate of need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need. Any transfer after that time will be subject to the requirement that the service be provided consistent with the representations made in the application and any applicable conditions the Department placed on the certificate of need. Transfers resulting from death or personal illness or other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause. Transfers resulting from death shall not result in withdrawal.

§ 131E-190. Enforcement and sanctions.

(a) Only those new institutional health services which are found by the Department to be needed as provided in this Article and granted certificates of need shall be offered or developed within the State.

(b) No formal commitments made for financing, construction, or acquisition regarding the offering or development of a new institutional health service shall be made by any person unless a certificate of need for such service or activities has been granted.

(c) Repealed.

(d) If any person proceeds to offer or develop a new institutional health service without having first obtained a certificate of need for such services, the penalty for such violation of this Article and rules hereunder may include the withholding of federal and State funds under Titles V, XVIII, and XIX of the Social Security Act for reimbursement of capital and operating expenses related to the provision of the new institutional health service.

(e) The Department may revoke or suspend the license of any person who proceeds to offer or develop a new institutional health service without having first obtained a certificate of need for such services.

(f) The Department may assess a civil penalty of not more than twenty thousand dollars (\$20,000) against any person who knowingly offers or develops any new institutional health service within the meaning of this Article without a certificate of need issued under this Article and the rules pertaining thereto, or in violation of the terms or conditions of such a certificate, whenever it determines a violation has occurred and each time the service is provided in violation of this provision. In determining the amount of the penalty the Department shall consider the degree and extent of harm caused by the violation and the cost of rectifying the damage. A person who is assessed a penalty shall be notified of the penalty by registered or certified mail. The notice shall state the reasons for the penalty. If a person fails to pay a penalty, the Department shall refer the matter to the Attorney General for collection. For the purpose of this subsection, the word "person" shall not include an individual in his capacity as an officer, director, or employee of a person as otherwise defined in this Article.

(g) No agency of the State or any of its political subdivisions may appropriate or grant funds or financially assist in any way a person, applicant, or facility which is or whose project is in violation of this Article.

(h) If any person proceeds to offer or develop a new institutional health service without having first obtained a certificate of need for such services, the Secretary of Health and Human Services or any person aggrieved, as defined by G.S. 150B-2(6), may bring a civil action for injunctive relief, temporary or permanent, against the person offering, developing or operating any new institutional health service. The action may be brought in the superior court of any county in which the health service facility is located or in the superior court of Wake County.

(i) If the Department determines that the recipient of a certificate of need, or its successor, is operating a service which materially differs from the representations made in its application for that certificate of need, the Department may bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized for injunctive relief, temporary or permanent, requiring the recipient, or its successor, to materially comply with the representations in its application. The Department may also bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized to enforce the provisions of this

subsection and G.S. 131E-181(b) and the rules adopted in accordance with this subsection and G.S. 131E-181(b).